Food and Drug Administration
Dockets Management Branch
Room 1061, HFA-305
5630 Fishers Lane
Rockville Maryland 20852

Food and Drug Administration Modernization Act of 1997
(FDAMA)

Suggestions FOR FDA in general

1. **What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?**

I propose that the Agency reorganize and tighten it's regulatory authority. FDA can only do what the Agency is justified to do. I believe we already have the tools, however, the Agency needs good managers to apply them. I believe that the Agency should do these four things and, in my estimation, seventy (70%) of the FDA's mission will run properly and satisfy our biggest concern, the consumer. The other thirty (30%) will be used for the new "state-of-the-art" science that may arise. Again the people designated to this thirty (30%) percent should understand how to properly apply the new science into FDA's jurisdiction, which is to regulate. The four steps areas follows:

Implementation and enforcement of **clear and direct** instructions and procedures to manufacturers, with frequent establishment inspections by FDA.

Implementation and enforcement of regulations, which will regulate vehicles, used in transmitting food through interstate commerce, with frequent inspections.

Implementation and enforcement of **clear and direct** instructions and procedures for food retailers, with frequent inspections;

Implementation of a central system in each Center that will keep track of food manufacturers, retail establishments, etc. in order for FDA to keep efficient, useful, and close files on the industry that we regulate. This way FDA will probably be able to foresee many problems before they arise, just by keeping good records of food, drug, and cosmetic establishments. For example: As the recall technician for FDA for nine years, I would notice when a product or recalling firm repeatedly violated the FD&C Act. Eventhough, I would alert my supervisor, nothing would ever be done. The people in these centralized units in each Center will watch for things like that. Once retail establishments, manufacturers, etc., realize that FDA is one step in front of them, they will begin to respect us and comply with the regulations we enforce.

Communication with the public should be modified tremendously. FDA should become more integrated into the consumer lives with PSA's, commercials, etc. Each Center should have a strong Public Affairs/Press group to disseminate vital information to the public.

2. **What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a products life cycle?**

FDA should maintain extensive maintenance of complaints, adverse reactions, and serious-illnesses related to the consumption and/or usage of any food, drug, or cosmetic and remember that it's a regulatory Agency. The overseers of this system should keep very close and open communication with FDA management to ensure communication throughout the specific Centers. Any new information concerning a regulated product by FDA should be forwarded to the prospective Center and disseminated throughout that Center for the general knowledge of the employees. There should also be a task group in place (i.e. CFSAN Health Hazard Evaluation Board) in each Center to evaluate the seriousness of the health risk, if any, related. If there is a health risk related to a certain product or usage there of, FDA should modify it's

regulation to include the scientific discovery. Information of modifications of a regulation or implementation of a new regulation should be disseminated to the appropriate Center employees and then FDA in whole. The appropriate unit (i.e. Press Office/Consumer Education Staff) should ensure that the information is disseminated to the public. This unit should weigh the importance/seriousness of the issue at hand in order to decipher how the information will be disseminated. Urgent information and/or regulation modifications should be disseminated through 30 & 60 second PSA 's. Non-urgent information should be included into upcoming speeches of FDA representatives to industry, information hotline, brochures, fliers, and listed in FDA press releases, etc.

3. **What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?**

Public service announcements (PSA's) and commercials for radio and television are the best way to obtain the attention of the greatest amount of people at one time. FDA should produce good PSA's to inform the public on whatever important/urgent issue FDA is tackling at the moment. PSA'S should run for at least a month. In the PSA's you give the specific product Center's centralized numbers and address for complaints and/or information staffs. Then, the information hotline, center complaint unit, brochures, fliers, press releases, etc. will continually educate and enforce the action as other FDA staffers rewrite and/or modify existing regulations.

4. **What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?**

I believe the Agency should reevaluate the importance of communication between FDA and the public. You must ensure that the unit responsible in each Center for educating the public and working with the press has substantial resources, since the burden will rest on this unit to disseminate the information.

5. **What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and /or evaluation of our modernization efforts?**

I believe you should focus on completion of the processes and reviews named by Industry as complex or unclear. Once clear and defined routes are established, communication will grow because there will be less to communicate about. Industry and FDA will have an understanding of how a specific system works. When situations and circumstances alter from that system, FDA and Industry will have a real issue to communicate about.

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